PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
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6th Floor
330 University Avenue
TORONTO, Ontario
Canada, M5G 1R7

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)* 23 July 2007 (23-07-2007)

Applicant's or agent's file reference
9577-60 KAM

FOR FURTHER ACTION
See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/CA2007/000550	03 April 2007 (03-04-2007)	03 April 2006 (03-04-2006)

International Patent Classification (IPC) or both national classification and IPC
IPC: ***A61K 9/36*** (2006.01), ***A61J 3/00*** (2006.01), ***A61K 47/38*** (2006.01), ***A61K 9/16*** (2006.01), ***A61K 9/22*** (2006.01), ***A61K 9/62*** (2006.01)

Applicant
ODIDI, ISA ET AL

1. This opinion contains indications relating to the following items :

- [X] Box No. I — Basis of the opinion
- [ ] Box No. II — Priority
- [X] Box No. III — Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- [ ] Box No. IV — Lack of unity of invention
- [X] Box No. V — Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- [ ] Box No. VI — Certain documents cited
- [X] Box No. VII — Certain defects in the international application
- [X] Box No. VIII — Certain observations on the international application

2. FURTHER ACTION
If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/CA	Date of completion of this opinion	Authorized officer
Canadian Intellectual Property Office Place du Portage I, C114 - 1st Floor, Box PCT 50 Victoria Street Gatineau, Quebec K1A 0C9 Facsimile No.: 001-819-953-2476	11 July 2007 (11-07-2007)	Nasreddine Slougui 819- 956-6132

Form PCT/ISA/237 (cover sheet) (April 2007)

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   [X] the international application in the language in which it was filed

   [ ] a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. [ ] This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material

      [ ] a sequence listing

      [ ] table(s) related to the sequence listing

   b. format of material

      [ ] on paper

      [ ] in electronic form

   c. time of filing/furnishing

      [ ] contained in the international application as filed.

      [ ] filed together with the international application in electronic form

      [ ] furnished subsequently to this Authority for the purposes of search.

4. [ ] In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

Box No. III **Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of :

[ ] the entire international application

[X] claim Nos. 52 and 54-56

because:

[X] the said international application, or the said claim Nos. 52 and 54-56 relate to the following subject matter which does not require an international search *(specify)* :

Claims 52 and 54-56 are directed to a method for treatment of the human or animal body by surgery or therapy, are not required to be searched nor is a written opinion required by this Authority. Regardless, this Authority has established a written opinion based on the alleged effect or purpose/use of the product defined in claims 52 and 54-56.

[ ] the description, claims or drawings *(indicate particular elements below)* or said claim Nos. are so unclear that no meaningful opinion could be formed *(specify)* :

[ ] the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed *(specify)*:

[ ] no international search report has been established for said claims Nos.

[ ] a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

[ ] furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

[ ] furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

[ ] pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rule 13*ter*.1(a) or (b).

[ ] a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.

[ ] the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

[ ] See Supplemental Box for further details.

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	None	YES
	Claims	1-51, 53, 57-74	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-51, 53, 57-74	NO
Industrial applicability (IA)	Claims	1-73	YES
	Claims	None	NO

2. Citations and explanations :

Cited Documents:

D1: US 2006/0003001 (Devane et al), 05 January 2006
D2: US 5004614 (Forum Chemicals Ltd), 02 April 1991
D3: US 5000962 (Schering Corporation) 19 March 1991
D4: EP157695 (Forest Laboratories Inc), 09 October 1985
D5: CA2286684 (Odidi Isa et al), 29 October 1998

Novelty step:

The cited D1-D3 disclose a controlled release delivery device with a core comprising an active ingredient which is coated with a polymeric material comprising different ratios of one or more pharmaceutically water- insoluble polymer, such as ethylcellulose, to one or more pharmaceutically acceptable water-soluble polymer, such as hydroxypropylmethylcellulose. Particularly, in D1, it is disclosed that the thickness of the polymer in the formulations, the amounts and types of polymers, and the ratio of water-soluble polymers to water-insoluble polymers are generally selected to achieve a desired release profile of the drug. The organosolvent and the anti-tacking agent are considered as excipients disclosed in these cited documents. Furthermore, processes of producing these controlled release delivery device as well their uses in different therapies are also disclosed. Therefore, the alleged invention contained in the instant claims is not novel and thus, a novelty step cannot be acknowledged for the claims 1-51, 53 and 57-74 according to Article 33(2) of the PCT because they include subject matter described in D1-D3.

Inventive step:

Claims 1-51, 53 and 57-74 do not meet the criteria set for obviousness by Article 33(3) of the PCT as the claims lack novelty, they also lack an inventive step.

Moreover, if the novelty objection is overcome, then, these claims will lack an inventive step with regards to D4 or D5 in view of D1-D3. D4 discloses a controlled release tablet of acid ascorbic comprising a carrier comprised of ethylcellulose and hydroxypropylmethylcellulose in a ratio approximately of 50/50 or 1/1 and excipients. D5 discloses a controlled release pharmaceutically active substance comprising a pharmaceutically

.....continued on Supplemental Box

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted :

Item 1: Claims 1-74 do not comply with Article 6. 4(c) of PCT in that all dependent claims referring back to a single previous claim, and all dependent claims referring back to several previous claims, shall be grouped together to the extent and in the most practical way possible.

Item 2: Claims 12 and 60 do not comply with Article 6 of the PCT, the expression "and or" should be "and/or"

Item 3: Claim 57 do not comply with Article 6 of the PCT, the second "the" in line 3 of the claim should be removed.

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made :

Item 1:Claims 1, 2 and 21 do not comply with Article 6 of the PCT in that there is a broad statement at the point c alleged invention. The statement is so broad that it embraces all possible means without qualification for solving the problem facing the inventor, and is in effect no more than a re-statement of the problem or the desired result.

Item 2: Claim 2 is unclear and does not comply with Article 6 of the PCT. A claim containing a negative expression such as "does not comprise" is objectionable in that claims should generally set forth what the allegec invention is or does, and not what it isn't or does not do.

Item 3: Claims 32 and 59 are indefinite and does not comply with Article 6 of the PCT. The inclusion of 110% causes ambiguity.

Item 4: Claims 54-57 are indefinite and does not comply with Article 6 of the PCT. The inclusion of "suitable" causes ambiguity.

Item 5: Reference to the name of "Carbomer" on page 23; "Aspirin" on page 28; "Cabosil", "Syloid", "Compritol", "Stear-O-Wet" and "Myvatex TL" on page 37 and "Carbowax" on page 38; should be identified a: trademarks according to Article 5 of the PCT.

Item 6: The description does not comply with the Article 5 of the PCT as the ratio "110%" described on page 4: line 23 and page 46, line 30 leads to an ambiguity and a lack of clarity.

Item 7: The description does not comply with Article 5 of the PCT. All documents referred to in the descriptior an application must be available to the public. Reference to the document on page(s) 1, line(s) 2 must be delete or replaced by its corresponding patent number or publication number.

Item 8: The drawing of Figure 1, do not comply with Article 7(1) of the PCT. The drawing does not adequately provide for the illustration of the alleged invention. It should be specified that this controlled profile corresponc to the drug methylphenidate, described in the example 2. Also, on one of the axis of the drawing, the expressic "% dissolvec" should be "% dissolved".

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of Box V

active substance, a fisrt polymer of ethylcellulose, a second polymer component comprising a mixture of hydroxyethylcellulose and hydroxypropylmethylcellulose. It would have been obvious for a person skilled in the art to combine the teachings of D4 or D5 in view of of D1, D2 or D3 or in view of the sate of art to reach the present contemplated controlled release delivery device for controlled reelase of an active ingredient comprising a core particle with a polymeric coat comprising a mixture of a water soluble gel forming polymer and a water insoluble polymer in a dry weight ratio of from about 20:80 to about 50:50. Varying the ratios of the water-soluble and the water-insoluble polymers cannot constitute a basis for patentability unless an outstanding result is achieved. Thus, claims 1-51, 53 and 57-74 appear to be obvious in the light of the cited documents in this report and therefore do not comply with the criteria set by Article 33(3) of the PCT for inventive step.

Industrial Applicability:

Claims 1-74 appear to meet the criteria of industrial applicability according to Article 33(4) of PCT.